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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,037	02/09/2004	Paul G. Yock	13854.4004	1520

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ORRICK, HERRINGTON & SUTCLIFFE, LLP
IP PROSECUTION DEPARTMENT
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EXAMINER

MARVICH, MARIA

ART UNIT	PAPER NUMBER
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1633

MAIL DATE	DELIVERY MODE
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06/24/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/776,037	Applicant(s) YOCK ET AL.	
	Examiner MARIA B. MARVICH	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-104 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-7, 15, 16, 18-31, 33-36, 45, 49-52, 54-62, 64, 66, 68, 69, 79-85, 87, 89, 92, 101 and 103 is/are allowed.
- 6) ☒ Claim(s) 8, 10-12, 37-42, 44, 46-48, 67, 70-77, 90, 91, 93-100, 102 and 104 is/are rejected.
- 7) ☒ Claim(s) 13, 14, 17, 32, 37, 43, 45, 49, 50, 53, 63, 65, 67, 68, 69, 74, 76, 78, 86, 88, 90, 92, 97 and 99 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/28/08 has been entered.

Claims 1-104 are pending in this application.

This application is a reissue of United States Patent Number 6,346,098.

The current amendment comprises unacceptable markings. As opposed to use of *double* brackets when deleting items of *less than 5 characters*, applicants have denoted any deletion by use of single brackets. For purposes of compact prosecution, the amendment has been entered, however, note must be taken of the proper means of indication deletions. As well, partial deletions of words are improper. For example, in claim 1 the amendment “to [produce a] disrupt[ion in]”, should have indicated deletions by strikethrough of “produce a” and “disruption” and inserted --disrupt-- by underlining.

Oath/Declaration

The oath is objected to as.

It does not identify the mailing address of each inventor. A mailing address is an address at which an inventor customarily receives his or her mail and may be either a home or business address. The mailing address should include the ZIP Code designation. The mailing address may be provided in an application data sheet or a supplemental oath or declaration. See 37 CFR 1.63(c) and 37 CFR 1.76. Specifically, the mailing address of Peter Fitzgerald is missing.

Response to Argument

Applicants' intent to send a new oath is acknowledged.

Claim Objections

Claims 32, 37, 63, 65, 67, 74, 76, 78, 86, 88, 90, 97 and 99 are objected to because of the following informalities: claims 1, recite "producing disruptive passageways there through" whereas it would be proper to recite --thereof-- to clarify that the passageways are in the wall of the vessel.

Claims 32, 63, 65, 74, 76, 86, 88, 97 and 99 recite "having an occlusion device downstream of the site of administration" whereas in fact -- having an occlusion device to occlude the vessel downstream of the site of administration --.

Claims 37 and 78 recites "retroinfusing a fluid into a vascular vessel" in order to infuse the agent into an interstitial space. However, the claim doesn't recite that the fluid comprises the agent and hence the claim should be amended to recite -- retroinfusing a fluid comprising the agent into a vascular vessel--. Absent this indication, it is not clear how the agent is introduced.

Claims 67 and 90 are objected to for recitation that "distention facilitates the disruption" is inaccurate. The distention does not facilitates disruption rather the --distention leads to disruption--.

Appropriate correction is required.

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Claims 17 and 53 objected to under 37 CFR 1.75 as being a substantial duplicate of claims 16 and 52. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Claims 15 and 51 are drawn to methods of retroinfusing under pressure sufficient to comprises the integrity of a call of said vein to produce disruptive passageways. The specification teaches that such a condition is disruption of the vessel. While the recitation in claims 16 and 52 also recite that the method leads to distention, the recitation in claims 17 and 53 that the pressure is sufficient to disrupt the walls is redundant.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8, 1-0-12, 37-42, 44, 46-48, 67, 70-77, 90, 91, 93-100, 102 and 104 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of retroinfusing an agent into a vascular vessel under pressure and/or to produce mechanical stress such that a wall of the vein is disrupted wherein the integrity of the wall is compromised leading to disruptive passageways, does not reasonably provide enablement for any other embodiment. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. **This is a new rejection necessitated by applicants' amendment.**

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The test of enablement is whether one skilled in the art could make and use the claimed invention from the disclosures in the patent coupled with information known in the art without undue experimentation (*United States v. Telectronics, Inc.*, 8 USPQ2d 1217 (Fed. Cir. 1988)). Whether undue experimentation is required is not based on a single factor but is rather a conclusion reached by weighing many factors (See *Ex parte Forman*, 230 USPQ 546 (Bd. Pat. App. & Inter, 1986) and *In re Wands*, 8USPQ2d 1400 (Fed. Cir. 1988); these factors include the following:

The instant claims are drawn to a method of locally administering an active agent to a host wherein the agent as part of a flowable formulation or a fluid delivery vehicle thereof is introduced into the vessel. The method is designed to cause disruptions in the vessel such that the agent moves into interstitial space. Specifically, the claims recite that the method "disrupts a wall of said vessel wherein the integrity of the wall is compromised producing disruptive passageways thereof for said agent to enter an interstitial space of aid host through said disruptive passages". Claims 8, 1-0-12, 37-42, 44, 46-48, 67, 70-77, 90, 91, 93-100, 102 and 104 are drawn quite broadly to any condition that leads to the disruptive passageways. However, the specification only discloses retroinfusion of the agent in a fluid such that mechanical stress is of sufficient magnitude resulting in the disruption. And, "a preferred means of providing the desired mechanical stress is to produce a high pressure environment in the target vascular site that is sufficient to provide the desired mechanical stress. The pressure of the high pressure environment that is produced in these embodiments may vary depending on the nature of the vascular deposition site, i.e. whether it is a vascular site of small volume, large volume, the blood pressure at the vascular deposition site, and the like. While exact pressures vary depending on

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the nature of the vascular deposition site, in many embodiments the pressure of the vascular deposition site is elevated to a value of at least about 50 mm Hg, usually at least about 60 mm Hg, where in certain embodiments the pressure may be elevated to a value that is at least about 1000 mm Hg or higher.”

As explained by applicants’ these disruptive passageways are distinct from naturally occurring pores that be treated to enhance pore diameter. For example, Wolffe et al teach a method involving a retrograde approach with increased permeability of the vessels that is increased by intravascular hydrostatic pressure by the fluid delivery. Specifically, in col 11, line 39-41, Wolffe et al teach, "biologically active molecules that affect permeability interact with a specific receptor or enzyme or protein with the vascular cell to change the vessel's permeability". The specification does not teach a condition other than mechanical stress such as increased pressure that leads to disruptive passageways wherein the integrity of the vessel wall is compromised. However, given the broad nature of the claims, it would require undue experimentation to determine those conditions other than mechanical stress and pressure that would result in disruptive passageways that are distinct from natural enhancement of pore openings for passage of agent would the interstitial space.

Conclusion

Claims 17, 32, 37, 53, 63, 65, 67, 74, 76, 78, 86, 88, 90, 97 and 99 are objected to because informalities.

Claims 8, 10-12, 37-42, 44, 46-48, 67, 70-77, 90, 91, 93-100, 102 and 104 are rejected.

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Claims 1-7, 15, 16, 18-31, 33-36, 45, 49-52, 54-62, 64, 66, 68, 69, 79-85, 87, 89, 92, 101 and 103 are allowed.

Claims 9, 13, 14, 43, 45, 49, 50, 68, 69 and 92 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARIA B. MARVICH whose telephone number is (571)272-0774. The examiner can normally be reached on M-F (7:00-4:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, PhD can be reached on (571)-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Maria B Marvich, PhD
Primary Examiner
Art Unit 1633

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Primary Examiner, Art Unit 1633

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